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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/041,556	01/10/2002	Wilfried Lubisch	33827-US-009	2746

26474 7590 07/23/2004

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1350 CONNECTICUT AVENUE, N.W.
WASHINGTON, DC 20036

EXAMINER

COLEMAN, BRENDA LIBBY

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 07/23/2004

7

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/041,556

Applicant(s)

LUBISCH ET AL.

Examiner

Brenda Coleman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 May 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 and 10-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 10-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>5/7/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-8 and 10-13 are pending in the application.

This action is in response to applicant's amendment filed May 7, 2004. Claim 1-4, 6 and 10 were amended, claim 9 was cancelled and claim 13 is newly added.

Response to Amendment

Applicant's arguments filed May 7, 2004 have been fully considered with the following effect:

1. The applicants' submission of the oath/declaration indicating the specification to which the oath or declaration is directed is herein acknowledged.
2. With regards to the 35 U.S.C. § 112, first paragraph rejection labeled paragraph 3) of the last office action, the applicant's amendments and remarks have been fully considered but they are not persuasive. The applicants failed to comment on the 35 U.S.C. § 112, first paragraph rejection of claims 1-12 which is directed "prodrugs" of the compounds of formula I.

Claims 1-8, 10-12 and newly added claim 13 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, for reasons of record and stated above.

3. With regards to the 35 U.S.C. § 112, first paragraph rejection labeled paragraph 4) of the last office action, the applicant's amendments and remarks have been fully

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considered but they are not persuasive. The applicants stated that claim 8 is a composition claim, not a method of treatment claim. The rejection should not apply to claim 8. The applicants also stated that claim 10 has been amended to more specifically recite the diseases and disorders being treated as supported by the application. However, at the time of filing of the present application, the nexus between the Applicants' claimed diseases or disorders and PARP inhibitors was not known in the art. While the some of the specific diseases listed in claim 10 have been indicated by the applicants to have a nexus with PARP inhibitors, this does not provide enablement for all of those diseases and/or disorders listed as well as claim 13, which is any and all diseases associated with PARP inhibitors. Treatment of diseases based solely on their efficacious in inhibiting the activity of at least one poly(ADP-ribose) polymerase does not provide for the treatment of every disease and/or disorder claimed herein. Not all diseases and/or disorders are treatable, let alone preventable. There is no evidence that any of the compounds instantly embraced have any one utility generically embraced in claim 13 or specifically recited in claim 10. Where structure sensitivity exists (in the pharmaceutical art) degree of testing must be representative of claims' scope. Note *In re Fisher* 166 USPQ 18; *In re Surrey* 151 USPQ 724. Thus the uses being urged are not in currently available form based on the activity relied on and the specification provides only a starting point for further research. Note *Genentech vs. Novo Nordisk* 42 USPQ 2d 1001. It is difficult to treat many of the disorders claimed herein. Instant claim language embraces disorders not only for treatment but for **prophylaxis** which is not remotely enabled. It is presumed in the prevention of the

diseases and/or disorders claimed herein there is a way of identifying those people who may develop tumours, etc. There is no evidence of record, which would enable the skilled artisan in the identification of the people who have the potential of becoming afflicted with the disorders claimed herein.

Claims 10 and newly added claim 13 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, for reasons of record and stated above.

4. The applicant's amendments and arguments are sufficient to overcome the 35 U.S.C. § 112, second paragraph rejection labeled c), d), e), f) and g) of the last office action, which are hereby **withdrawn**. However with regards to the 35 U.S.C. § 112, second paragraph rejections labeled a) and b) the applicant's amendments and remarks have been fully considered but they are not persuasive.

a) The applicants' stated "when w is O in the definition of B wherein L_v-YM_w , one of ordinary skill in the art would appreciate that Y does not exist". However, this is not stated as such and if Y does not exist when w is O then it is not known what is attached to L.

b) The applicants' stated that they have amended the claims to address items a) through e). However, the definition of E has not been amended with respect to the missing point of attachment of the moiety $-NHCOCH_2X^4$ in the rejection labeled b).

Claims 1, 2, 4-8, 10-12 and newly added claim 13 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for reasons of record and stated above.

5. The applicants' amendments and arguments are sufficient to overcome the 35 U.S.C. § 101 rejection, labeled paragraph 6 in the last office action, which is hereby **withdrawn**.

6. The applicants' amendments and arguments are sufficient to overcome the 35 U.S.C. § 102, anticipation rejection, labeled paragraph 7 in the last office action, which is hereby **withdrawn**.

7. With regards to the objection to claim 12 the applicant's amendments and remarks have been fully considered but they are not persuasive. A multiple dependent cannot depend on two different claims unless it is stated in the alternative. See MPEP § 608.01(n).

In view of the amendment dated May 7, 2004, the following new grounds of rejection apply:

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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8. Claims 1-8 and 10-13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

a) The amendment to the definition of G^2 , where the diazepine ring is substituted on the nitrogen atom by R^7 is not defined in the specification with respect to the genus.

b) The amendment to the term prodrug where the prodrug is an ether prodrug is not defined in the specification with respect to the genus.

Applicant is required to cancel the new matter in the reply to this Office action.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

9. Claims 1-8 and 10-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

a) Claims 1, 2, 4-8 and 10-13 are vague and indefinite in that it is not known what is meant by "atoms can also carry one or two =O groups" in the definition of B. It is not known what atoms this pertains, the use of a comma after sulphur is unclear.

- b) Claims 1, 2, 4-8 and 10-13 are vague and indefinite in that it is not known what is meant by “=O groups” in the definition of B. It is believed that the applicants intended an oxygen atom and not the numeral 0.
- c) Claims 1, 2, 4-8 and 10-13 are vague and indefinite in that it is not known what is meant by the comma in the moiety L_v ,- YM_w within the definition of B.
- d) Claims 1, 2, 4-8 and 10-13 are vague and indefinite in that it is not known what is meant by “0” in the definition of Y. It is believed that the applicants intended an oxygen atom and not the numeral 0.
- e) Claims 1, 2, 4-8 and 10-13 are vague and indefinite in that it is not known what is meant by C^1 - C^6 -alkyl in the definition of Y. It is believed that the applicants intended subscripts.
- f) Claims 1-4, 8 and 10-13 are vague and indefinite in that it is not known what is meant by $-(D)p-(E)_s-(F^1)_q-G^1-(F^2)_r-G^2-G^3$ in the definition of R^4 . It is believed that the applicants intended p to be a subscript.
- g) Claims 1, 2-4, 8 and 10-13 are vague and indefinite in that it is not known what is meant by the moiety $-c(=O)-$ in the definition of E. It is believed that the applicants intended a capital c.
- h) Claims 1-4, 6, 8 and 10-13 are vague and indefinite in that it is not known what is meant by “atoms can also carry one or two =O groups” in the definition of G^1 . It is not known what atoms this pertains, the use of a comma after sulphur is unclear.

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- i) Claims 1-4, 8 and 10-13 are vague and indefinite in that it is not known what is meant by "atoms can also carry one or two =O groups" in the definition of G^3 . It is not known what atoms this pertains, the use of a comma after sulphur is unclear.
- j) Claims 1-8 and 10-13 are vague and indefinite in that it is not known what is meant by " SO_2NH_2 or SO_2-R^8 " in the definition of R^{42} . It is believed that the applicants intended an oxygen atom and not the numeral 0.
- k) Claims 1-8 and 10-13 are vague and indefinite in that it is not known what is meant by the definition of R^{11} , R^{12} and R^{13} in K, R^5 , R^6 and R^7 , which can, independently of each other, assume the same meaning as R^1 , and thus there is two different definitions for the variables R^{11} , R^{12} and R^{13} .
- l) Claims 1-8 and 10-13 are vague and indefinite in that it is not known what is meant by " $0-C_1-C_4$ -alkyl" in the definition of R^{91} . It is believed that the applicants intended an oxygen atom and not the numeral 0.
- m) Claim 6 is vague and indefinite in that it is not known what is meant by the definition of R^4 where R^4 is $G^1-F_{0,1}^2-G^2-G^3$.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda Coleman whose telephone number is 571-272-0665. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on 571-272-0674. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Brenda Coleman
Primary Examiner Art Unit 1624
July 19, 2004